

Amendments to the Drawings:

The Examiner has objected to the drawings in that the drawings do not show “the cylindrical foam sleeve having a smaller normal expanded diameter than a diameter of the lumen of said catheter.” New Figure 6D has been added to the drawings to illustrate a version of the cylindrical foam sleeve which has a normally expanded diameter less than the diameter of the lumen of the catheter.

Newly added Figure 6D is not only supported by the language of Claim 5 as the Examiner has pointed out, “wherein said cylindrical foam sleeve has a smaller normal expanded diameter than an outer diameter of said catheter” but is also supported by statements made in the Specification, such as on page 8, “Typically, the normal expanded diameter of the foam sleeve is smaller than the diameter of the catheter used to delivery the embolization device” and again on page 10 “The normal expanded diameter of the foam material may be smaller than the diameter of the catheter used to deliver the embolization device.” Accordingly, the version of the embolic device as illustrated in Figure 6D is clearly supported and disclosed by the specification and the claims. It is believed that with the addition of new Figure 6D and the brief description of this Figure in the specification, the Examiner’s objection to the drawings have been overcome.

REMARKS/ARGUMENTS

The Cited References

U.S. Patent No. 6,238, 403 to Greene, Jr., et al., discloses an embolization device in which a plurality of expansible embolization elements are spaced apart and are disposed along a single filamentous carrier. The carrier is described as being “preferably a length of nickel/titanium wire.” The foam elements are placed on this wire carrier. A plurality of spacers, described as “microcoil spacers” are mounted on the wire and placed between adjacent foam elements to maintain spacing between these elements.

U.S. Patent No. 6,165,193 to Greene, Jr., et al., simply discloses a foam element mounted on wire 22 which is attached to a coil deployment mechanism. The wire element 22 serves as a short “retention” wire for purposes of attaching the foam element to the distal end of the release mechanism.

U.S. Patent No. 4,890,612 to Kensey, merely shows a sealing device for sealing a puncture or incision formed in the tissue of a patient.

The Rejection

Claims 1 through 14 have been rejected “under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 42 of U.S. Patent No. 6,723,108.” The Examiner has also indicated that a Terminal Disclaimer “in compliance with 37 C.F.R. 1.321(c) may be used to overcome. . .[this] provisional rejection. . .” Attached hereto is a Terminal Disclaimer based upon the expiration date of the ‘108 patent.

Claims 1 through 9 and 11 through 14 have been rejected “under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,238,403 to Greene, Jr. et al.” In addition, Claims 1, 2, 4 and 8 have been rejected “under 35 U.S.C 102(e) as being anticipated by U.S. Patent No. 6,165,193 to Greene, Jr. et al.”

Claim 10 has been rejected “under 35 U.S.C. 103(a) as being unpatentable over Green, Jr. et al. ‘403 in view of U.S. Patent No. 4,890,612 to Kensey.”

Remarks

With respect to Claim 1 and its dependent Claims 2 through 10, these claims positively recite “an embolization device comprising an elongated helical coil formed into a secondary helical configuration and a cylindrical foam sleeve disposed about said coil.” In other words, these claims positively recite an elongated helical coil and also recite that the elongated helical coil is formed into a secondary helical configuration. Neither of these limitations, which are recited in Claim 1 and its dependent Claims 2 through 10 are shown or disclosed by either of the Greene, Jr., et al. patents. More particularly, the ‘403 Greene Jr. patent discloses a carrier 14, described as a filamentous carrier, or wire, which extends through the foam elements 12 in order to support the foam elements relative to each other. The carrier 14 is described as being “preferably a length of nickel-titanium wire.” While there is disclosed a helical coil 16, this helical coil serves as a spacer to retain the foam elements in relationship to each other along the wire carrier 14.

While the plural foam elements are spaced along a helically shaped wire, there is no suggestion of an elongated helical coil formed into a secondary helical configuration with foam material disposed on such a coil. In fact there is no suggestion of an elongated helical coil formed into a secondary helical configuration.

With respect to the ‘193 patent to Greene, Jr., this patent also discloses a foam element 30 which surrounds a wire. This wire referred to as a “retention wire” merely serves the function of retaining the foam material at the distal end of the deployment system. Clearly, there is no suggestion in this reference of a foam sleeve disposed about a coil and certainly no

suggestion of a foam sleeve disposed about a coil which takes the form of an elongated helical coil formed into a secondary helical configuration.


These structural limitations, as positively recited in independent Claim 1 and its dependent Claims 2 through 10, form an important part of the claimed invention. This structure, as recited, in the claims cannot simply be ignored.

With respect to independent Claim 11 and its dependent Claims 12 through 14, these claims, as amended, positively recite "an embolization device comprising an elongated coil and a cylindrical foam sleeve disposed about substantially the entire length of said coil." As discussed, the '403 and '193 patents to Greene merely show a foam material carried by a wire carrier 14 in the case of the '403 patent, and a wire support element 22 in the case of the '193 patent. Again there is no suggestion in these references of disposing a cylindrical foam sleeve about substantially the entire length of an elongated coil.

With respect to the rejection of Claim 10 as being unpatentable over the '403 patent in view of U.S. Patent No. 4,890,612 to Kensey, this claim includes all of the limitations of dependent Claim 9 and independent Claim 1, including the limitations previously discussed. Neither of these patents disclose or suggest this structure.

With these amendments, Applicants submit that Claims 1 through 14 clearly define patentable invention over the references of record. Accordingly, it is respectfully submitted that this application is now in condition for allowance and notification of such action is respectfully solicited.

Respectfully submitted,

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